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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/529,575 04/14/00 ROURKE

F 7042-R

024967 QM12/0713  
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EXAMINER

WEBB, J

ART UNIT

PAPER NUMBER

3761  
DATE MAILED:

7  
07/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/529,575

Applicant(s)

ROURKE ET AL.

Examiner

Jamisue A. Webb

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-33 and 35-40 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6 6) ☐ Other:

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 8/22/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. In the information disclosure statement, the applicant has made a statement that a copy of all the references are not submitted due to the fact that they were submitted and considered in parent application US 09/041,232, and under 37 C.F.R. 1.98(d) the applicant did not have to file a copy of the references if it claimed priority under 35 USC 120 and the parent file contained those references. However, the instant application did not claim priority under 35 USC 120 to application US 09/041,232. In order for priority to be claimed under 35 USC 120 the applications must be copending, application 09/041,232 was abandoned before the instant application was filed. The examiner has obtained most of the foreign references, however there were three of them (see signed copy of the IDS) that were not considered. It should be noted that any references submitted after this office action is mailed out will be considered to be received after the first office action, and are subject to the rules outlined in 37 CFR 1.98.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 3761

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 21-33, and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roe (5,607,760) in view of Kasahara et al. (JP 04-182,423).

4. Roe teaches a diaper containing a topsheet coated with a semisolid lotion and immobilizing agent. The lotion may be applied to the topsheet non-uniformly where portions of the surface do not have any lotion on it.

Roe however fails to provide the lotion containing a protease inhibitor. Kasahara et al. teaches protease inhibitors in the form of a lotion or emulsion where the inhibitors include trypsin inhibitor, aprotinin, soybean trypsin inhibitor, leupeptin, p-aminobenzamidine, and derivatives of guanidinobenzoic acid which may be used alone or in combination. (page 5, line 27-29 and page 6, lines 3-5). The examiner considers  $IC_{50}$  to be an inherent property in the protease inhibitor itself. Due to the fact that Kasahara discloses many claimed protease inhibitor, then the examiner considers Kasahara to disclose all the claimed IC values.

It would have been obvious to one skilled in the art at the time the invention was made to use the protease inhibitor composition of Kasahara on the topsheet of Roe, to reduce skin irritation and prevent diaper rash. (see Kasahara page 5).

#### *Allowable Subject Matter*

5. Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3761

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jamisue A. Webb whose telephone number is (703) 308-8579. The examiner can normally be reached on M-F (8:30 - 5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John G. Weiss can be reached on (703) 308-2702. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jaw

July 11, 2001.

